

Application Number 10/826,925

Amendment in response to Office Action mailed October 16, 2007

REMARKS

This Amendment is responsive to the Office Action dated October 16, 2007. Applicant has amended claims 24, 38, 41, 51, 55, 83 and 94, and cancelled claims 1-23 and 57-82. Claims 24-56 and 83-99 are pending with claims 44 and 99 withdrawn due to restriction.

Information Disclosure Statements

Applicant appreciates the Examiner's careful consideration of the Information Disclosure Statements mentioned in the Office Action, and apologizes for the number of references cited in more than one Information Disclosure Statement.

Applicant notes that the returned Form 1449 for the Information Disclosure Statement dated September 29, 2005 does not include the Examiner's initials next to the "International Search Report and Written Opinion for Corresponding PCT Application Serial No. PCT/2005/008801, mailed July 26, 2005 (11 pages)." Applicant respectfully requests that the Examiner indicate her consideration of this reference by providing another copy of the Form 1449 with this reference initialed.

Objections to the Drawings

The Office Action objected to the drawings as failing to comply with 37 CFR § 1.84(p)(5), because FIG. 5 included reference numeral 104, which was not mentioned in the description. Applicant has amended paragraph [0103] of the specification to include reference numeral 104. Withdrawal of this objection is respectfully requested.

Claim Objection

The Office Action objected to claim 83 and suggested replacing "and asleep" on line 7 with "and when the patient is asleep." Applicant has amended claim 83 accordingly. Withdrawal of this objection is respectfully requested.

Allowable Subject Matter

The Office Action indicated that claims 48-50 are allowable in their present form. The Office Action also indicated that claim 38 would be allowable if the double patenting rejection

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were overcome and the claim was rewritten in independent form including all of the limitations of the base claim and any intervening claims and claims 39-42, 55 and 88 would be allowable if the claims were rewritten in independent form including all of the limitation of the base claim and any intervening claims. Applicant appreciates these indications of allowable subject matter.

Claim Rejections Under 35 U.S.C. § 102(e)

The Office Action rejected claims 24-26, 30, 31, 43 and 45 under 35 U.S.C. § 102(e) as being anticipated by Stahmann et al. (US 2005/0039745, herein referred to as "Stahmann '745"); and rejected claims 51, 52, 54, 56, 83, 84, 89, 93, 94 and 96-98 under 35 U.S.C. § 102(e) as being anticipated by Stahmann et al. (US 2005/0085738, herein referred to as "Stahmann '738"). Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the amended claims. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

Claims 24-26, 30, 31, 43 and 45

For example, Stahmann '745 fails to teach or suggest a medical system comprising a processor that determines a value of a metric that is indicative of sleep quality based on values of at least one physiological parameter determined during delivery of therapy by a medical device according to a therapy parameter set and associates the sleep quality metric value with the therapy parameter set, and a memory that receives the sleep quality metric value and an indication of the therapy parameter set associated with the sleep quality metric value, as recited by amended independent claim 24.

Stahmann '745 describes detecting disordered breathing and adapting a therapy to mitigate the disordered breathing. In support of the rejection of claim 24, the Office Action noted that the processor of Stahmann '745 must somehow identify the current therapy and somehow relate or associate the current therapy with the sleep quality metric in order to assess and/or change the current therapy based on the sleep quality metric, as disclosed by Stahmann '745.

However, even if the sleep quality metric taught by Stahmann '745 is somehow related or associated with the current therapy, a point which Applicant does not concede, Stahmann '745

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fails to disclose or suggest a memory that receives the sleep quality metric value and an indication of the therapy parameter set associated with the sleep quality metric value. As recognized in the statement of reasons for allowance of claims 48-50, nothing in Stahmann '745 discloses or suggests a memory that receives a sleep quality metric value and an indication of the therapy parameter set associated with the sleep quality metric.

Claims 51, 52, 54, 56, 83, 84, 89, 93, 94 and 96-98

With respect to amended independent claim 51, Stahmann '738 fails to disclose or suggest a medical system comprising an implantable medical device that determines a plurality of values of a metric that is indicative of sleep quality based on values of at least one physiological parameter, and associates each of the sleep quality metric values with at least one of a plurality of therapy parameter sets that was used by the medical device to deliver the therapy to the patient when the values of the at least one physiological parameter were determined. Stahmann '738 lacks any disclosure that would even remotely disclose or suggest this requirement of amended claim 51.

Furthermore, Stahmann '738 also fails to disclose or suggest a medical system comprising an external programming device including a display that receives sleep quality metric values and indications of therapy parameter sets with which the sleep quality metric values are associated from the implantable medical device and presents sleep quality information to a user via the display based on the sleep quality metric values and the indications. Stahmann '738 describes methods and systems for organizing information related to sleep and/or events occurring during sleep. For example, Stahmann '738 describes obtaining information relating to patient physiological and activity conditions via a sleep quality data collection and analysis unit.¹ Stahmann '738 does not disclose or suggest that the display receives or presents information based on the sleep quality metric values and indication of therapy parameter sets with which the sleep quality values are associated.

¹ Stahmann '738, paragraph [0159].

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With respect to independent claim 83, Stahmann '738 fails to disclose or suggest a medical system comprising a processor that determines a value of a metric that is indicative of sleep quality based on identifications of when the patient is attempting to sleep and when the patient is asleep, and associates the sleep quality metric value with a therapy parameter set used to deliver the therapy to the patient when at least one of when the patient is attempting to sleep and when the patient is asleep were identified.

In support of the rejection of claim 83, the Office Action cited Stahmann '738 as teaching a processor that identifies when the patient is attempting to sleep and when the patient is asleep and determines a value of a sleep quality metric based on identification of when the patient is attempting to sleep and when the patient is asleep. However, Stahmann '738 does not disclose or suggest associating a sleep quality metric value with a therapy parameter used to deliver a therapy to the patient when at least one of when the patient is attempting to sleep and when the patient is asleep were identified. Instead, Stahmann '738 discloses storing sleep quality information in a sleep logbook assessable via a user interface. For at least these reasons, Stahmann '738 fails to disclose or suggest each and every element of independent claim 83.

The applied references fail to disclose each and every limitation set forth in independent claims 24, 51 and 83. Claims 25, 26, 30, 31, 43 and 45 are dependent upon claim 24, claims 52, 54, and 56 are dependent upon claim 51, and claims 84, 89, 93, 94 and 96-98 are dependent upon claim 83. These dependent claims are also in condition for allowance. For at least these reasons, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 24-26, 30, 31, 43, 45, 51, 52, 54 and 56 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

The Office Action rejected claims 27, 35, and 37 under 35 U.S.C. § 103(a) as being unpatentable over Stahmann '745 in view of Stahmann '738; rejected claims 28, 29, 33, and 34 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745 in view of Auphan (US 2005/0143617); rejected claim 32 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745 in view of Lee et al. (US 2005/0065560, herein referred to as "Lee '560"); rejected claim 36 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745 in view of Stahmann '738

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and further in view of Sun et al. (US 6,273,856, herein referred to as "Sun"); rejected claims 46 and 47 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745 in view of Lee et al. (US 2005/0061320, herein referred to as "Lee '320"); rejected claims 53 and 95 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738 in view of Sun; rejected claim 85 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738 in view of Stahmann et al. (US 2005/0043772, herein referred to as "Stahmann '772"); rejected claims 86 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738 in view of Stahmann '772 and further in view of Sheldon (US 5,593,421); rejected claim 87 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738 in view of Burnes et al. (US 2004/0215269); rejected claim 90 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738 in view of Roizen et al. (US 2001/0031930); claim 91 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738 in view of Stahmann '745; and rejected claim 92 under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738 in view of Auphan. Applicant respectfully traverses these rejections. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Each of claims 27-29, 32-37, 46, 47, 53, 85-87, 90-92 and 95 depends from one of independent claims 24, 51 and 83. For at least the reasons previously described with respect to independent claims 24, 51 and 83, these dependent claims are also in condition for allowance. None of the secondary references cited in the Office Action overcomes the above-identified deficiencies of the Stahmann references with respect to the independent claims.

Additionally, Applicant respectfully disagrees with the Office Action's finding that several of the dependent claims included intended use statements. Applicant submits that, "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used."² Applicant submits that the claims clearly define the invention and requests consideration of all elements of Applicant's claims.

As one example, with respect to claim 47, the applied references fail to disclose or suggest a medical device comprising at least one of a trial neurostimulator and a trial pump.

² MPEP 2173.05(g)

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Claim 47 further limits the independent claim by defining functional limitations of the medical device. Applicant requests consideration of these claim limitations in the subsequent Office Action.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 27-29, 32-37, 46, 47, 53, 85-87, 90-92 and 95 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

Rejection for Obviousness-type Double Patenting:

The Office Action provisionally rejected claim 24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 11/081811 to Heruth et al. (herein referred to as "Heruth '811").

The Office Action also provisionally rejected claims 24, 38 and 43 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 3 of copending application Heruth '811 in view of Stahmann '745.

The Office Action also provisionally rejected claims 35-37 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 5 of copending application Heruth '811 in view of Stahmann '745 and further in view of Stahmann '738.

The Office Action also provisionally rejected claim 24 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 11/081,857 to Heruth et al (herein referred to as "Heruth '857").

The Office Action also provisionally rejected claim 51 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 14 of copending application Heruth '857.

Applicants note the provisional status of this rejection. Accordingly, Applicants will address this issue if and when the rejection is formally applied.

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CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Office Action's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

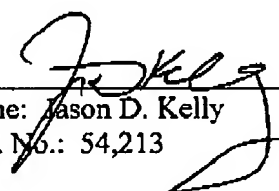
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

1/16/08

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